

Governor's Office of Health Policy and Finance
April 29, 2004

MEMO ON RE-IMPORTATION OF PRESCRIPTION DRUGS

Individuals who take brand name prescription drugs for chronic conditions can achieve substantial savings by purchasing their drugs from Canadian pharmacies. Generic drugs, on the other hand, are typically less expensive in the United States.

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs. In addition to testing drugs for safety and efficacy, the FDA sets standards for their manufacture and distribution. It approves drugs for use that are manufactured in accordance with FDA standards, including packaging and labeling standards, and distributed through the FDA or a state regulated distribution chain. It defines all other drugs as unapproved.

Re-importation of drugs strictly refers to purchasing from wholesalers or pharmacies in a foreign country drugs that were originally manufactured in the U.S. and bringing those drugs into the U.S. Re-importation of drugs manufactured in the U.S. are specifically prohibited under the Food, Drug, and Cosmetic Act (*21 U.S.C. § 381(d)(1)*). However, the FDA also has a policy allowing the importation of drugs for personal use under limited conditions (*FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage for Personal Importations*). In practice, neither the FDA nor the U.S. Customs enforces any restriction on individuals bringing prescription drugs purchased abroad into the U.S.

More generally, the term is used to cover all drugs that are imported into the U.S. from wholesalers or pharmacies in a foreign country. While the manufacturer may conform to FDA standards and undergo FDA inspections, the drugs sold to foreign wholesalers or pharmacies are outside the jurisdiction of the FDA or state regulators and are not approved by the FDA and therefore not allowed to be sold in the U.S. (*U.S.C. § 355*).

The FDA has outlined the potential liability for those who violate the prohibitions on importing unauthorized drugs. They include both civil and criminal violations and escalate from misdemeanors to felonies for repeat offenses (*FDA letters to the California Attorney General's Office and the Kullman Firm*).

The recent Medicare Prescription Drug bill has reauthorized the Secretary of Health and Human Services to allow the re-importation or importation of drugs from foreign suppliers but only if he assures their safety. (*Medicare Rx Drug Discount and Security Act of 2003*)

MODELS

There are several methods or models for purchasing prescription drugs from Canadian pharmacies. The following describes methods that are currently used or proposed.

Bus Trips or Individual Visits to Canadian Pharmacies

Individuals have for some time been purchasing prescriptions from Canada if they live near the border, when on vacation there, or in one organized purchasing efforts such as publicized bus trips. The Maine Council of Senior Citizens has sponsored bus trips to Canada for a number of years to provide individuals the opportunity to purchase prescription drugs from a Canadian pharmacy. These buses first visit a physician on the Maine side of the border with a “border license” from New Brunswick. (See border license below) This physician takes the prescriptions written by the bus riders’ personal physician, examines the individual if appropriate, rewrites the prescription on a Canadian script, and faxes the prescription to the Canadian pharmacy. The Canadian pharmacy reviews and fills the prescription. The bus continues its trip to the Canadian pharmacy, and the bus riders pick up the medication. The New Brunswick pharmacy fills prescriptions for a 6 month supply and allows an individual to phone in one refill request. This provides the bus rider a one year supply for one bus trip. The council makes 2 trips a year accommodating 20 to 24 riders on each trip.

Canadian pharmacies typically dispense drugs in containers that have been pre-packaged by the manufacturer as a further precaution against contamination and counterfeiting. The Canadian system does not allow wholesalers to breakdown bulk packages from manufacturers. Canadian pharmacies also do not typically breakdown manufacturers packages to smaller amounts.

Prescriptions from Physicians with Border Licenses

New Brunswick allows Maine physicians licensed to obtain a border license for a modest fee. It was initially intended to accommodate individuals living along the New Brunswick-Maine border where the nearest doctor may be in Maine and/or the nearest pharmacy in New Brunswick

Affiliated Healthcare Systems (AHS) of EMMC in Bangor has established a Pharmacy-Canada Prescription Program (PCR_x) (<http://www.bigbluea.com/canadarx>) which uses the border license option to assist individuals in obtaining medications from Canadian pharmacies. It has a web page where individuals research the cost of prescription drugs in Canada and assists them to obtain the drugs when they are less expensive in New Brunswick.

Individuals must complete a 2-page Customer Profile listing drug allergies and other medication they are taking, obtain a prescription written by a Maine physician with a border license, and send both to PCR_x. PCR_x forwards the prescription and the profile on to a pharmacy in New Brunswick which reviews and fills the prescription and mails it to the individual. PCR_x also has relationships with Canadian physicians who will review and rewrite prescriptions written by American physicians who do not have a border license. This rewriting by Canadian physicians is similar to the procedures used by internet or mail order pharmacies. The predominant business, however, is in processing

prescriptions from physicians with border licenses. EMMC has encouraged its physicians who write prescriptions for chronic illnesses to obtain border licenses. Recently AHS sent a letter to many Maine primary physicians describing the PCRx program and explaining how to obtain a border license.

United Health Alliance

The Vermont based United Health Alliance, and its president and CEO Elizabeth Wenner, pioneered a way of importing drugs from Canada without requiring patients to travel to Canada. The Alliance system used an FDA loophole which allowed an individual to import a limited supply of FDA-approved drugs, prescribed by a licensed American doctor, for personal use. Doctors obtained the drugs for a patient by faxing to a Canadian pharmacy a form which listed the doctor's Drug Enforcement Agency Number. This allowed the physician to purchase prescription drugs for office use. The physician included the patient's credit card number for payment. Canadian law bars its pharmacies from processing prescriptions not ordered in Canada. However, the physician ordered the medicine not as a prescription but merely as "supplies for the office." The drugs were mailed to the doctor's office where the patient picked the package up unopened. In this way, the doctor was not buying and dispensing drugs, and the pharmacist was not filling a prescription. *(June 14, 2000 article, UHA's website, <http://www.unitedhealthalliance.com/News.htm>)* This method has been superseded by mail order and Internet pharmacies.

Internet and Mail Order Pharmacies

Individuals can also deal directly with a Canadian Internet or mail order pharmacy or a Pharmacy Benefits Manager (PBM) in Canada. The individual sends the prescriptions written by their personal physician to the Internet pharmacy along with the medical history form requested by the pharmacy including a list of allergies and other medications taken by the individual. The Internet pharmacy contracts with a Canadian licensed physician to review the prescription and history information and if appropriate approves the prescription and rewrites it as a Canadian script. A new Internet pharmacy accrediting organization, Internet and Mailorder Pharmacy Accreditation Commission (IMPACTM), has been established to review and accredit Internet pharmacies in Canada and other countries. To add a safety measure, mail order and internet pharmacies typically only sell prescription drugs in amounts packaged by the manufacturer.

As a first step in his plans to reduce prescription drug costs for residents of Minnesota, Governor Pawlenty has initiated the development of a website to facilitate the purchase of personal use prescription drugs from Canadian pharmacies. The Maine Citizens Leadership Fund has sponsored a website, Maine Rx Express, (<http://www.rxmaine.com>) that provides information on how to purchase prescription drugs from Canada and provides links to Canadian pharmacies. Congressman Tom Allen's website (<http://tomallen.house.gov>) also provides links to Canadian pharmacies that serve U.S. customers.

New Hampshire and Rhode Island have also established websites where citizens can link to Canadian mail order pharmacies. In addition New Hampshire's Governor Benson plans to use Canadian mail order pharmacies to purchase prescription drugs for prison inmates. As explained Keith Herman on his staff: "The state corrections dept. pharmacist can contract directly with a Canadian pharmacy to provide individual inmates with prescription drugs. Since we can treat inmates as individuals, we feel we can implement this option under the federal individual exemption."

American Store Front Pharmacies

Private business interests have seen the opportunity in lower Canadian prices and have set up businesses to process prescriptions. They collect customer medical profile information and prescriptions from clients and forward them to PBM or pharmacy partners in Canada. They serve as a go-between for American customers who find it difficult to deal directly with a Canadian pharmacy. Rx Depot is a storefront that has recently been the subject of FDA scrutiny and been ordered by the courts to cease operations. As outlined below, the FDA does not sanction purchases of drugs from other countries but has concentrated enforcement actions on commercial operations.

Elizabeth Wenner of the United Health Alliance voices concern about the proliferation of storefront pharmacies. The storefronts are not typically staffed by pharmacists and serve mainly as brokers between Canadian pharmacies and U.S. consumers. She feels they should be regulated more closely or even closed. (*Telephone conversation with Lars Rydell*)

Government Employee Plans

In the current tight economic situation, some local governments have benefited from the lower prices offered by Canadian Internet pharmacies by "carving-out" prescription drug coverage from their health insurance plans. They establish relationships with selected Canadian PBM's and pharmacies that will provide the types and quality of service they require. This help includes determining which drugs are cheaper in Canada. The "carved-out" drug coverage plan would use American sources for non-narcotic drugs that are cheaper in the U.S. and encourage employees to purchase drugs that are cheaper in Canada from the Canadian supplier. The Canadian supplier requires the employee to complete a medical profile form and engages a Canadian physician to review and rewrite the prescription.

The city of Springfield, Massachusetts has gained considerable notoriety for aggressively pursuing this approach and has negotiated an arrangement with the Canadian PBM, CanaRx. It limits orders primarily to refill prescriptions of higher cost long term maintenance drugs and excludes narcotics. In order to monitor for adverse side effects, they require individuals to fill first time prescriptions through the health plan's PBM or local pharmacy. To maintain a distance from the transaction, it required the employee to contact the Canadian supplier directly, and the city's pharmacy plan reimburses the employee for the cost of the drug, review by the Canadian physician, shipping, and other costs. To encourage employees to use the Canadian supplier, the city's plan waves the

employee co-pay if the total cost, including the co-pay, is less than the cost from the American supplier. Springfield estimates annualized savings of between \$2.75 and \$3 million. The estimate is based on 2,500 participants among 10,000 employees who have at least one 30-day script. They have a total of 20,000 employees and retirees. In addition, participating employees save the co-payment.

The state of Minnesota is in the process of developing a plan for its employees but has not released the details.

The governor of Illinois, Rod R. Blagojevich, initiated a study of the safety and potential cost savings if state employees and retirees purchased prescription drugs from Canada. (*Illinois "Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies,"* <http://www.affordabledrugs.il.gov/feasibility.cfm>) If all employees and retirees participated, the report estimated savings of \$20.7 million to enrollees and \$34.3 million to the state. The report indicates a more realistic projection is 33% participation for a savings of \$6.9 million and \$11.4 million respectively. It explored several options and favored an approach that provides additional safe guards for the employees by establishing a more direct relationship between the state's health plan and the Canadian supplier. Participation would still be voluntary, but the state would set the term in a contract with the supplier, and the supplier would bill the state plan directly. The governor has stated that he would not proceed with the plan without FDA approval and has made a formal request. The report also recommends requiring individuals to purchase their drugs through a "primary pharmacist." The primary pharmacist would provide oversight and care management of all drugs taken by an individual, a further protection to assure the safety of the program.

Governor Blagojevich sent a formal request to the Commissioner Thompson at the Department of Health and Human Services (HHS) on December 22, 2003 and issued a press release requesting permission for Illinois to set up a pilot importation program. (<http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=3&RecNum=2549>) A spokesperson for HHS responded the next day indicating that HHS "cannot" approve the request as "there were no legal provisions allowing Illinois to be designated a test state."

The FDA has also responded to an inquiry by the Kullman Firm in New Orleans, LA which sponsors and/or administers employer-sponsored health plans. Kullman asked about the potential civil and criminal liability of health plans which directly or indirectly support the importation of prescription drugs from Canada. (*FDA letter to Kullman,* <http://www.fda.gov/ora/import/kullman.htm>) The letter reiterates the FDA's opposition to the importation of drugs and states that "Those who aid and abet a criminal violation of the Act, or conspire to violate the Act, can also be found criminally liable." It goes on to say that

"Beyond articulating these general principles, we are unable to advise you as to whether, in the factual scenario that you set forth in your letter, Expedite Rx, the plan sponsor, the plan administrator, the plan member, SPC [Global Technologies, Ltd], the Canadian pharmacy, or the Canadian doctor could be found liable under one or more of these avenues. We are

reluctant to give an advisory opinion, especially because potential liability is a very fact-specific inquiry. However, any party participating in this kind of import plan does so at its own legal risk. Of course, if FDA were to take enforcement action in this scenario, our highest enforcement priority would not be actions against consumers.”

The FDA’s opinion of possible penalties is discussed in the FDA section below.

Penobscot Nation and Maine Council of Senior Citizens.

The Penobscot Nation (PN) and the Maine Council of Senior Citizens (MCSC) applied to the U.S. Department of Health and Human Services for a \$200,000 grant for a special planning study to "establish specific data that would show if prescription medicines can be safely imported." (*PN and MCSC August 26, 2002 letter to Secretary Thompson*) The letter indicates that the University of Maine would assist the PN and MCSC to "establish the proper research and study techniques and preserve all collected data." The study would provide the information needed by Secretary Thompson to authorize, following the U.S. Safe Drug Act, the PN and MCSC to:

- Establish a system to import prescription drugs from Canada by contracting with a Canadian pharmaceutical wholesaler.
- Import the drugs to a secure facility at Indian Island on the Penobscot Reservation.
- Market the drugs to retail pharmacies in Maine.

The program would engage the University of Maine on an ongoing basis to evaluate the process to assure that the safety and efficacy of the imported drugs is maintained. The purpose of the program would be to allow Mainers to purchase prescription drugs at their local pharmacy at prices comparable to those available at Canadian pharmacies.

The congressional delegation has written letters of support and is currently working to arrange a meeting with Secretary Thompson

Schematically, the various options are presented in the following table.

	Bus Tours	Mail Orders and Border Licenses	Third Party Website Vets and Posts Web Addresses of Canadian Internet Pharmacies	Storefront Pharmacy	Springfield, MA model	Illinois model
Voluntary purchasing	X	X	X	X	X	X
Insurance reimbursement		Some Health Plans	Some Health Plans	Some Health Plans	X	Direct payment by state
Incentive					X	X
Limit eligible Canadian pharmacies or PBM				X	X	X

Limit eligible prescriptions*					X	X
Government Plan Contract with Canadian PBM						X

* Narcotics cannot be purchased over the internet or by mail order.

PHARMACEUTICAL COMPANIES

The pharmaceutical companies and their trade organization group, Pharmaceutical Research and Manufacturers of America (PhRMA), oppose the importation of drugs from other countries. They cite the safety concerns enumerated by the FDA. In addition they raise the concern that sanctioning the purchase of drugs from other countries will reduce their revenues and restrict their ability to fund research and development on future life saving and life enhancing drugs. Governor Pawlenty agrees that the companies may raise a valid concern but questions why American consumers and particularly those that do not have a PBM that can negotiate somewhat lower prices, should foot a disproportionate share of the manufacturers' R&D costs.

Some pharmaceutical companies have raised the prices on their drugs sold to Canada, though compared to the drug inflation in the U.S., the Canadian increases are in a more moderate 4% to 8% range.

The companies have also started to implement their "threat" to limit the supply of drugs they sold to Canada to reflect the Canadian domestic market. David MacKay, Executive Director of the Canadian International Pharmacy Association has written in an April 2004 notice that "CIPA member pharmacies are reaching a crisis point at it relates to stocking sufficient supplies of drugs from Pfizer, Eli Lilly and AstraZeneca. Each of these companies has effectively "blacklisted" our pharmacies and as such, they are preventing us from accessing adequate supply to meet our current patient demand."

CANADIAN SITUATION

As reported in the NYT (*Bernard Simon, Curtailing Medicines from Canada, NYT. November 11, 2003*) "The drug industry agreed to the [price] controls [in Canada] in the early 1990's in exchange for the government ending a system of compulsory licensing, which allowed generic versions of drugs to be produced before the normal expiry of patents." In theory, though perhaps more difficult in practice, if the drug industry does not uphold its side of the agreement and stops or curtails supplies of drugs to Canada, Canadian authorities could loosen restrictions on the manufacture of generic equivalents. If the manufacturers limited supply, Canada could also arrange to purchase additional supplies through other countries.

The FDA also has some support in Canada. Barbara Wells, executive director of the National Association of Pharmacy Regulatory Authorities (NAPRA) in Ontario, Canada, says the practice of U.S. residents filling prescriptions in Canada is an issue that her organization is concerned about. "Our members do not feel that Canadian pharmacists

should be breaking laws of jurisdictions in which their patients reside," she says. (*FDA Consumer magazine, September-October 2002, Imported Drugs Raise Safety Concerns by Michelle Meadows*) The NYT article cited above also suggests that "Traditional pharmacies have thrown their support behind the drug manufacturers as they view the online drugstores as competitors for drug supply and of greater concern pharmacists." Aside from the general opinion that the Canadian system was not designed to regulate sales to U.S. customers, the Canadians do not raise safety concerns about drugs sold in Canada.

The impact on the Canadian pharmacy infrastructure may be a significant problem if the demand from the U.S. increases dramatically. Pharmacists may be attracted to the Internet pharmacies from other less attractive locations. Rural pharmacies, in particular, may experience increased difficulty in attracting and retaining pharmacists. The impact would be doubly jarring if the U.S. created a domestic solution for the high cost of drugs, and the Canadian pharmacies' new U.S. customers suddenly returned to U.S. suppliers. Given the difference in population size, there may not be a sufficient number of Canadian pharmacies to serve more than a small percentage of the U.S. market. David MacKay, executive director of the Canadian International Pharmacy Association (CIPA) has stated that he doubted Canadian pharmacies could meet the demand of large programs. An AP/Minneapolis Star Tribune, 12/22/03 story reported that CIPA ended negotiations with Wisconsin officials on a re-importation over concerns the program could lead to prescription drug shortages in Canada.

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) has the responsibility of assuring the safety of prescription drugs in the US. It has tried to fulfill this obligation by creating a "closed" distribution system of supply where the "pedigree" of drugs can be tracked from manufacturer through wholesale supplier and repackagers to the retail pharmacy and consumer. This supply chain is overseen by the FDA and state government agencies that license and regulate wholesalers and retail pharmacies. The FDA has developed agreements with other countries to allow the FDA to inspect drug manufacturers in those countries to ensure that they comply with FDA requirements for drugs shipped to the U.S.

The FDA has not negotiated agreements that allow it to inspect other aspects of those countries' distribution chain or to require that the drugs shipped to or used by other countries are manufactured to meet all FDA standards, including packaging requirements. While it accepts the regulatory procedures and jurisdiction of state governments as part of its "closed" distribution system of controls, it has not entered into agreements or accepted the regulatory procedures of other countries or Canadian provinces as sufficient to track the pedigree of drugs or protect the safety of the drug supply.

In order to protect US consumers from the possibility of contamination or counterfeit drugs introduced in a foreign country, the FDA requested and obtained statutory authority to prohibit the re-importation of drugs manufactured in the U.S. The Medicine Equity and Drug Act of 2000 and the recent Medicare Prescription Drug bill (*Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Sec 804(k)(1)(1)*) would allow the importation

of drugs manufactured in other countries, or the re-importation of drugs manufactured in the U.S. All, however, both Acts require that the Secretary of Health and Human Services certify to the Congress that the implementation that importation “pose no additional risk to the public's health and safety;” and “result in a significant reduction in the cost of covered products to the American consumer.” Neither the previous nor current Secretary has been willing to take that step.

Personal Use

The FDA’s current policies allow the importation of drugs for personal use, also referred to as compassionate use. The personal use guidance was first adopted in 1954, and it was modified in 1988 in response to concerns that certain AIDS treatments were not available in the United States. The original intent was to allow individuals with serious conditions, such as a rare form of cancer, to get treatments that are legally available in foreign countries but are not approved in the United States. The FDA’s Regulatory Procedures Manual, subchapter on Coverage of Personal Importations provides the following operating guidance for FDA personnel. “FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.” (http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html)

The FDA does not interpret these provisions as an approval of purchase of drugs from Canadian pharmacies over the Internet, by mail order, or organized special purpose bus trips. While it has concentrated its enforcement activities on commercial enterprises like RxDepot, it reserves the right to prohibit the importation by individuals. The attached FDA letters to the California Attorney General’s Office and the Kullman Firm outline the FDA’s interpretation of current statutes. Although it has no enforcement jurisdiction over foreign commercial entities, the FDA has sent “warning letters” to them including CanaRx used by the town of Springfield. (*See the attached FDA letter to CanaRx.*) In its letter to CanaRx, the FDA recognizes that CanaRx’s location outside the U.S. “limit[s] the FDA’s jurisdiction over certain aspects of its operations.” It goes on state that “we are reviewing our enforcement options. We are also forwarding information about these violations to the appropriate Canadian authorities for their review.”

The FDA outlined the potential liability faced by individuals and firms in the U.S. who import drugs in its letter to the California Attorney General’s Office and to the Kullman Firm as follows:

As noted in your letter, there are many potential avenues of civil and criminal liability for parties involved in violations of the Act. A court can enjoin violations of the Act. (21 U.S.C. § 332) A person who violates the Act can also be held criminally liable. (21 U.S.C. § 333) A misdemeanor violation of the Act is a strict liability offense. (*United States v. Dotterweich*, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1)). A violation that is committed with intent to defraud or mislead or after a prior conviction for violating the Act is a felony. (21 U.S.C. § 333(a)(2)) Separately, it is a felony to

knowingly import a drug in violation of the re-import prohibition. (21 U.S.C. § 333(b)(1)(A), 381(d)(1))

Those who can be found civilly and criminally liable include all who cause a prohibited act. (21 U.S.C. ' 331) ("The following acts and the causing thereof are hereby prohibited"). Those who aid and abet a criminal violation of the Act, or conspire to violate the Act, can also be found criminally liable. (18 U.S.C. " 2, 371)

In the larger picture, the FDA can cite examples of inadequate controls on the supply chains and the discovery of counterfeit or contaminated drugs purchased in other countries in general and Canada in specific. (*FDA News Release, September 29, 2003, FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments.*) There are occasionally safety issues or recalls of drugs with in the U.S. distribution system and FDA officials cite similar events in Canada where their ability to know about and respond to the incident is limited. (*Kaiser Foundation, Ask The Experts: Prescription Drug Re-importation Webcast, 12/2/2003.*) The FDA does not have the authority to regulate or even oversee or monitor the distribution systems in other countries. It also does not have the personnel to carry out such a task, even for one country, if it did have the authority. FDA officials agree that they could develop cooperative agreements with Canada and implement procedures to resolve some of the issues if they had the resources. (*Kaiser Foundation, Ask The Experts: Prescription Drug Re-importation Webcast, 12/2/2003.*)

This one-size-fits-all assessment, however, does not necessarily apply equally to all countries nor does the U.S. have a universally superior system compared to all other countries.

There are both opportunities and unintended incentives in the U.S. system that allow and reward criminal behavior. In its ongoing efforts to improve the effectiveness of the U.S. "closed" chain and drug pedigree tracking, the FDA has formed an internal Counterfeit Drug Taskforce to examine ways to improve the safety of the supply chain in the U.S. (http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.pdf) Among other process and technology improvements, an interim report of the taskforce considered certain policies and procedures of the Canadian and European Union systems. The practice in both Canada and Europe of requiring pharmacies to dispense drugs only in original manufacturers' packaging would reduce the concern with the introduction of contamination or counterfeit drugs during the process of repackaging of bulk quantities distributed by the manufacturer. (*FDA, Counterfeit Drug Taskforce Interim Report, October 2003, <http://www.fda.gov/oc/initiatives/counterfeit/report/qa.html>*)

The system of controlled and unified pricing in Canada and European countries reduces the incentive and opportunity for introducing adulterated drugs. The differential prices charged various classes of purchasers in the U.S. provides an incentive for unscrupulous dealers to break the chain of supply and divert drugs from low paying to high paying purchasers. Any break in the chain clouds the pedigree tracking and provides an opportunity for the introduction of counterfeit drugs. In addition, the practice of manufacturers selling bulk quantities of their oversupply of drugs at discount prices

provides the profit margin to allow an extended chain of small wholesalers to purchase and resell the discounted drugs before they reach the final wholesaler and retail distribution. The longer the chain the more difficulty it is to track the pedigree of the drugs shipped. Canada has a short chain with a limited number of wholesalers who distribute directly to retail pharmacies.

The report commissioned by Governor Blagojevich compared the Canadian system of regulating the manufacture, distribution, and sale of prescription drugs and concluded that it was equal to and, in the cases cited above as well as others, potentially superior to that achieved by the FDA and state regulators in the U.S.

Dr. Mark B. McClellan, the commissioner of the FDA, in a recent, November 18, 2003, trip to Canada tried to elicit the support of the Canadian Federal Health Department to clamp down on the export of drugs to the U.S. Diane Gorman, the assistant deputy minister in the Canadian federal health department commented at a joint news conference (*Washington Post*, November 18, 2003) that "At this stage, we don't have evidence of Canadian law being broken." "When we do have evidence of Canadian law being broken, we will act accordingly." She did not specify which laws might be of concern but implied they were the same as those applying to Internet or mail order pharmacies serving Canadian customers. In addition, she responded to the FDA's concern over the safety of drugs purchased from Canada by stating that "Canada's safety record is second to none internationally."

MAINE PHARMACY STATUTES AND PRACTICES

Maine pharmacy statutes have allowed Maine pharmacies to fill prescriptions written by physicians practicing outside of Maine. Prior to the 1987 recodification of the pharmacy statutes, pharmacies could fill prescriptions of written by New Hampshire, New Brunswick, and Quebec physicians. The 1987 recodification extended the provision to include physicians and certain other professions who are "licensed in the United States or Canada to dispense, conduct research with respect to or administer drugs in the course of professional practice or research." In a 1999 amendment, the permission was extended to "an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice." The stated intent of the 1999 amendment was to include all individuals who are licensed to dispense drugs. Patients of New Brunswick physicians could always have their prescriptions filled in Maine pharmacies.

New Brunswick prohibits its pharmacies from filling prescriptions unless they are written by a physician licensed in that province. However, it provides a relatively simple procedure to allow Maine physicians to obtain "boarder licenses" and allows New Brunswick pharmacies to fill prescriptions written by Maine physicians with boarder licenses.

Maine statute requires that any pharmacy "dispensing prescription medications by mail or carrier from a facility not located in this state to a patient who resides in Maine" (32

MRSA §13702, sub-§ 23) must register with the Board of Pharmacy (32 MRSA §13751 - §13754). In order for a pharmacy to register they must “identify the pharmacist licensed to practice in the State who will be the pharmacist in charge.” (32 MRSA §13752, sub-§2, ¶C) It further requires the pharmacist in charge to certify “that the facility is secure, suitable for operation as a drug outlet and in compliance with applicable federal and state laws, rules and regulations governing the practice of pharmacy.” (32 MRSA §13752-A, sub-§1, ¶B) These requirements currently prevent pharmacies in New Brunswick from registering with the Board of Pharmacy and prevent the Pharmacy Board from having any regulatory oversight.

Since it is a relatively longstanding practice of at least some Maine residents in border areas to purchase drugs from New Brunswick pharmacies and the practice seems to be increasing, it might be advisable to amend the Maine pharmacy statutes to extend the Pharmacy Board's oversight to cover pharmacies in New Brunswick that sell drugs to Maine residents. It would make the current practice legal under Maine statutes. More importantly, it would allow the state government to perform its role of protecting the safety of the prescription drug supply to Maine residents and eliminate the concern over the safety of prescription drugs purchased in New Brunswick. Amending the statutes would also eliminate any restriction in the Maine statutes on the state government's directing Maine residents who intend to purchase prescription drugs from pharmacies in New Brunswick to pharmacies regulated by the Pharmacy Board.

CONCLUSION

The FDA considers the sale of unapproved drugs to be illegal. Since the FDA does not approve any drug handled by a wholesaler or pharmacy not regulated by the FDA or a state, no drug supplied by a Canadian wholesaler or pharmacy is approved. Hence the FDA considers any importation or re-importation of drugs from Canada to be illegal. Its enforcement practices, however, are concentrated on commercial entities that make a profit. It currently does not have plans to take action against individuals who purchase drugs from Canada. (*Kaiser Foundation, Ask The Experts: Prescription Drug Re-importation Webcast, 12/2/2003.*) It “operational guidance” for FDA personnel allows them to “use their discretion to allow [importation of drugs] . . . for personal use.”

Though it is difficult to imagine the U.S. changing its pricing practices in the near future, it also does not seem reasonable that the importation of drugs from Canada would be a long term solution for U.S. consumers or a long term opportunity for Canadian pharmacies.

Maine state government could establish a user friendly website link to Canadian mail order pharmacies to assist citizens who choose to purchase prescription drugs from Canada. In order for the state to establish a program for its employees and retirees similar to that developed by Springfield, MA, it would have to amend its current pharmacy statutes. Assuming Maine would have the same mix and volume of prescription drug use and the same adoption rate as Springfield, the state could expect savings in the order of \$5.5 to \$6 million. If other public purchasers implemented similar

programs, the overall savings to state and local government would increase proportionate to the volume of use. In both cases, the state could strengthen quality control by entering into agreements with a limited number of pharmacies that conform to standards established by the state.

Enforcement actions by the FDA to prohibit state and local governmental entities from entering into agreements with foreign pharmacies or PBMs, or otherwise aiding or encouraging individuals to purchase drugs in Canada, would be the major potential liability.

Some possible initial steps would be:

1. Website Link to Canadian Mail Order Pharmacies. Develop a link on the State's website to Canadian Mail Order Pharmacies for Maine citizens who choose to purchase drugs from Canada
2. Border Licenses. To simplify the process of filling prescriptions in Canada and in retaining control by the employee's primary physician, the state could encourage physicians who write the most prescriptions to get border licenses from New Brunswick, e.g., family physicians, internists, oncologists. Information on applying for border licenses can be found at the College of Physicians and Surgeons of New Brunswick website. (<http://www.cpsnb.org/english/borderlicense.html>) The cost of the border license is \$100 a year plus an initial, one time, registration fee of \$100.
3. Analyze Prescription Use. The state could analyze what drugs are the most costly (cost X volume). As a help, the drugs that Springfield found are cost effective to import are listed on their website. (<http://www.springfieldmeds.com/TierList.htm>)
4. Establish a program following the Springfield model. Springfield (<http://www.springfieldmeds.com>) provided an incentive by waiving the co-pay for employees on those drugs that Springfield found to be cheaper in Canada if the employee ordered the drug from Canada. For drugs that are cheaper from their U.S. PBM, employees have to order through the U.S. PBM and pay a co-payment. To enhance the sweetener for ordering through Canada, the state could increase the co-pay on drugs ordered through the U.S. PBM for those drugs that are cheaper in Canada.

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